K 030795

AUG - 5 2003

510(k) Summary

GMP|Wireless Medicine LifeSync™ System

Classification Name: Radiofrequency Physiological Transmitter and Receiver
21 CFR 870.1920
Device Class: II
Product Code: 74 DRG

GMP Companies, Inc.
One East Broward Boulevard
Suite 1701
Fort Lauderdale, FL 33301

Phone: (954) 745-3510
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Contact: Ralph Jugo, Prepared: February 28, 2003

A. LEGALLY MARKETED PREDICATE DEVICE

The GMP|Wireless Medicine LifeSync™ System is substantially equivalent to the Mortara Ambulatory X-12 Telemetry Module that was cleared by FDA under K974149 on January 8, 1998.

B. DEVICE DESCRIPTION

The GMP|Wireless Medicine LifeSync™ System is comprised of 4 primary components and 1 accessory component: 1) a patient wearable 5-electrode array called the Continuous Leadwear™, 2) a patient wearable 6-electrode array called the Discrete Leadwear™, 3) LifeSync™ Patient Transceiver-with Armband , and 4) a LifeSync™ Monitor Transceiver. The accessory component is: 5) an optional Multi-Unit Battery Charger.

The LifeSync™ Patient Transceiver will be responsible for sampling ECG waveforms from the electrode array and converting these signals into digital data. It will then transmit this data over a wireless Bluetooth link to the Monitor Transceiver. The LifeSync™ Monitor Transceiver will reconstruct the analog signals from the received digital data and present these signals to the normal inputs of a standard Continuous Cardiac Monitor or Discrete Diagnostic ECG System. The LifeSync™ System has been validated for use with several ECG systems of various manufacturers.

C. INDICATIONS FOR USE

The GMP|Wireless Medicine LifeSync™ System is indicated for use when ECG monitoring is needed and a wireless cable-free connection is desired between the patient and the ECG Monitor. The LifeSync™ System will also transmit the patient respiration waveform for those ECG systems that include a respiration function.

D. INTENDED USE

The GMP|Wireless Medicine LifeSync™ System is intended for use as a radiofrequency signal transmitter and receiver of diagnostic electrocardiographic physiological signals which are displayed on the ECG monitors of various manufacturers' systems that have been validated for compatibility. ECG systems that are not currently wireless in operation will now be able to be used in a wireless fashion by virtue of being connected to the GMP system. The LifeSync™ System will also transmit the patient respiration waveform for those ECG systems that include a respiration function.

The GMP|Wireless Medicine LifeSync™ System will eliminate the wires between the ECG patient and the ECG monitor and will replace the traditional ECG cable with a radio link. The GMP|Wireless Medicine LifeSync™ System will support the standard 5-lead ECG hook-up (via the Continuous Leadwear™) for monitoring and has the capability to add the remaining V1-V6 precordial leads (via the Discrete Leadwear™) for 12-lead discrete ECG recording.

E. SUBSTANTIAL EQUIVALENCE SUMMARY

The GMP|Wireless Medicine LifeSync™ System is a medical device and has a similar indications for use statement as the predicate device. The differences do no alter the intended diagnostic effect--both devices have essentially the same intended use. The device also has the same technological characteristics as the predicate device. Since a comparison of the descriptive characteristics of the proposed and predicate devices may not be sufficiently precise to assure equivalence, performance data are provided. The results of the performance testing demonstrates substantial equivalence.

As recommended in the 11-5-98 FDA Guidance Documents for Industry – Diagnostic ECG Guidance, and Cardiac Monitor Guidance, substantial equivalence which is the primary basis for 510(k) concurrence, has been assessed and is demonstrated in this 510(k) submission by evaluating the LifeSync™ System for conformity to ANSI/AAMI EC11-1991 "Diagnostic Electrocardiographic Devices", ANSI/AAMI EC13-2002 Cardiac Monitors, Heart Rate Meters, and Alarms, and to ANSI/AAMI EC38-1998, "Ambulatory Electrocardiographs." The LifeSync™ System's patient Continuous and Discrete

Leadwear™ have also been assessed for conformity to ANSI/AAMI EC53-1995, "ECG Cables and Leadwires".

F. TECHNOLOGICAL CHARACTERISTICS

Both devices use electronic components to process and transmit ECG signals via a radiofrequency link. While the details of the transmission process are different, the basic technology is the same.

G. TESTING

In-vitro performance testing was conducted in accordance with the standards, ANSI/AAMI EC11 - 1991, "Diagnostic Electrocardiographic Devices" and ANSI/AAMI EC38-1998, "Ambulatory Electrocardiographs", ANSI/AAMI EC13 - 2002 "Cardiac Monitors, Heart Rate Meters, and Alarms", and AAMI/ANSI EC53 - 1995 "ECG Cables and Leadwires." That is, since the GMP device is intended and is labeled to be compatible with a number of manufacturers' diagnostic/discrete ECG and continuous cardiac monitoring systems, testing in accordance with the EC11, EC13, and EC38 standards was performed in order to assure compatibility between the LifeSync™ System and the ECG Systems that are covered by the standards.

The LifeSync™ system was tested to the requirements of EN 60601-1:1990 "Medical electrical equipment Part 1. General requirements for safety", IEC 60601-1-2:2001 "Medical electrical equipment Part 2. Collateral Standard: Electromagnetic compatibility", and IEC 60601-2-27:1994 "Medical electrical equipment Part 2. Particular requirements for the safety of electrocardiographic monitoring equipment", and it met all of the applicable requirements.

H. CONCLUSIONS

This pre-market notification has demonstrated Substantial Equivalence as defined and understood in Sections 513(f)(1) and 513(i)(1) of the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 5 2003

GMP Companies, Inc.
c/o Mr. Ralph Jugo
Director of Regulatory Affairs
One East Broward Blvd.
Suite 1701
Fort Lauderdale, FL 33301

Re: K030795
Trade Name: GMP Wireless Medicine LifeSync™ System
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver.
Regulatory Class: Class II (two)
Product Code: DRG
Dated: June 4, 2003
Received: June 5, 2003

Dear Mr. Jugo:

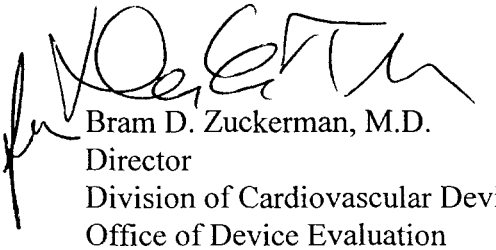
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: GMP|Wireless Medicine LifeSync™ System

Indications For Use:

The GMP|Wireless Medicine LifeSync™ System is indicated for use when ECG monitoring is needed and a wireless cable-free connection is desired between the patient and the ECG Monitor. The LifeSync™ System will also transmit the patient respiration waveform for those ECG systems that include a respiration function.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K030795

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____